GOVERNMENT OF INDIA
SCIENCE AND TECHNOLOGY
LOK SABHA

STARRED QUESTION NO:73
ANSWERED ON:05.03.2002
MEDICAL BIO TECHNOLOGY PRODUCTS
SUBODH MOHITE

Will the Minister of SCIENCE AND TECHNOLOGY be pleased to state:

(a) whether the Government have revamped the regulatory process for medical bio-technology products;

(b) if so, the details thereof;

(c) whether fast-track clearance mechanism has been put in place for plant bio-technology products;

(d) if so, the details thereof; and

(e) other measures taken by the Government to solve the problems relating to medical bio-technology products ?

Answer

MINISTER OF SCIENCE AND TECHNOLOGY (PROF. MURLI MANOHAR JOSHI)

(a) & (b) : Yes, Sir. Efforts have been made to streamline and speed up the regulatory process for medical biotechnology products. Recombinant medical products presently follow a three-tier regulatory mechanism as per the Rules 1989 under the Environment (Protection) Act, 1986. The Institutional Biosafety Committee(IBSC), Review Committee on Genetic Manipulation(RCGM) an Genetic Engineering Approval Committee(GEAC) in accordance have been functioning. Further, an eight member multi-disciplinary Recombinant Drug Advisory Panel has been constituted by the Ministry of Health for evaluation of rDNA derived therapeutic products (dr5ugs and pharmaceuticals) and to assist the office of the Drugs Controller General (India) to decide about market authorization of such products.

(c),(d) & (e) : Based on the recommendations of Confederation of Indian Industries (CII) and experts, a Single Window Mechanism for receiving all the applications on recombinant DNA products has been established in DBT with a designated nodal officer. Proforma for receiving the proposals has been put on DBT`s website. Time schedule for frequent meetings of RCGM and GEAC, a software for receipt of applications and ensuring more consultations with the experts are the measures put in place. The `Guidelines for Generating Pre-clinical and Clinical data for Recombinant Vaccines, Diagnostics and other Biologicals formulated by the Department of Biotechnology in November 1989 have become a part of the `Guidelines for the Clinical Trials on Pharmaceutical Products in India` issued by Central Drugs Standard Control Organization, Directorate General of Health Services. Training and awareness programme with stake holders have been organized. Efforts are on to continually speed up clearance procedure in consultation with the concerned departments/agencies.